Remarks

Status of the Claims following the Office action mailed 02/14/2007

Claims 17-32 are pending.

Claims 17-32 are rejected.

Amendments to the Claims

Claim 17 has been amended to incorporate the limitations of dependent claim 30, to include the step of lysing the red blood cells after staining (see, for example, the specification at page 15, lines 26-27), to specify that the antibodies are fluorophore-conjugated (see, for example, the specification at page 13, lines 23-25), and to describe the invention more clearly. Claim 30 has been canceled and claims 31 and 32, which depended from claim 30, have been amended to depend from claim 17.

The amendments to the claims do not introduce new matter. Applicants request entry of the amendments to the claims into the record.

Rejection of claims under 35 U.S.C. §112

I. Claims 17-32 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for lack of antecedent basis in claim 17, step (c). Applicants traverse for the reasons set forth, below.

Claim 17 has been amended to correct the lack of antecedent basis for binding of particular antibodies. Applicants further note that what the antibodies bind to, and the pattern of binding to cells of particular types, is clear from the descriptions in the specification of the recited classes of antibodies.

Applicants request reconsideration and withdrawal of the rejection of claims 17-32 under 35 U.S.C. §112, second paragraph, in view of the amendments and remarks.

II. Claims 17-29 were rejected under 35 U.S.C. §112, first paragraph, as lacking enablement in the specification for the method not reciting the use of at least one

dendritic cell subsetting antibody, the lysing of red blood cells, or the use of labeled antibodies. Applicants traverse for the reasons set forth, below.

Claim 17 has been amended to incorporate the limitations of dependent claim 30, which further specify the use of at least one dendritic cell subsetting antibody, to include the step of lysing red blood cells, and to specify that the antibodies are fluorophore-conjugated (i.e., labeled). Applicants believe that the amendment to claim 17 removes the basis for the rejection for claim 17 and for dependent claims 18-29.

Applicants request reconsideration and withdrawal of the rejection of claims 17-29 under 35 U.S.C. §112 in view of the amendments and remarks.

Rejection of claims under 35 U.S.C. §103

Claims 17-32 were rejected under 35 U.S.C. §103(a) as being unpatentable over Becton Dickinson Application Note 3, "Peripheral Blood Dendritic Cells Revealed by Flow Cytometry" ("App Note 3") in view of Becton Dickinson Application Note 1, "Detection of Intracellular Cytokines in Activated Lymphocytes" ("App Note 1").[1] Applicants traverse the rejection for the reasons set forth, below.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974) (see, also, *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970) "All words in a claim must be considered in judging the patentability of that claim against the prior art."). In addition, the must be a reason identified why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed. "[I]n formulating a rejection under 35 U.S.C. §103(a) based upon a combination of prior art elements, it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed." (Memorandum dated May 3, 2007, from Deputy Commissioner for Patent Operations to Technology Center Directors regarding the Supreme Court decision

[1] App Note 3, which listed contributors Olweus and Willmann on the last page, was cited as "Olweus et al." in the Office action. App Note 1, which did not list contributors, was cited as "Becton Dickinson" in the Office action. Applications herein have chosen a consistent abbreviation for these two application notes.

on KSR Int'l. Co., v. Teleflex, Inc., emphasis added). Applicants assert the rejection is improper because the cited prior art fails to teach or suggest all elements of the claimed methods and, furthermore, there is no reason that why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed.

The present invention provides methods that enable the characterization of dendritic cells by their expression of cell-surface activation markers in response to a dendritic cell activator (see the specification at page 12, lines 19-26). Claim 17 recites a combination of elements that includes contacting a whole blood sample with a dendritic cell activator (step (a)) and measuring the level of binding of the antibody specific for a dendritic cell surface marker as a measure of dendritic cell function (in step (d)).

App Note 3 teaches identifying dendritic cells using flow cytometry using various dendritic cell distinguishing antibodies and dendritic cell subsetting antibodies (using the terminology of the present specification), and "allows for the simultaneous detection, quantitation, and isolation of two distinct DC subsets in freshly isolated peripheral blood" (App Note 3, page 2, second column, last paragraph). App Note 3 does not teach or suggest contacting the sample with a dendritic cell activator before identifying dendritic cells or characterizing dendritic cells by their response to a dendritic cell activator.

App Note 1 teaches the detection of intracellular cytokines in activated lymphocytes (T-cells) using flow cytometry. App Note 1 does not teach activating dendritic cells (in contrast to Examiner's assertion in the Office action at page 10). Although contacting a sample of whole blood with a T-cell activator, depending on the T-cell activator, may also result in the activation of dendritic cells present in the sample, such spurious activation of dendritic cells is merely a byproduct in the methods of App Note 1, which teaches only the activation of T-cells. App Note 1 fails to make up for the teaching lacking in App Note 3.

The combined teachings of the cited reference fail to teach or suggest all elements of the claimed method, including contacting a whole blood sample with a dendritic cell activator (step (a)) and measuring the level of binding of the antibody specific for a dendritic cell surface marker as a measure of dendritic cell function (step

(d)). For this reason, *prima facie* obviousness of a claimed invention has not been established and the rejection should be withdrawn.

In addition, one of skill in the art at the time of the invention would not be motivated to modify the methods of App Note 3 to obtain the claimed method. App Note 1 teaches only activating T-cells, not dendritic cells, and one of skill in the art would not activate T-cells in order to characterize subsets of dendritic cells by their response to a dendritic cell activator. For this additional reason, *prima facie* obviousness of a claimed invention has not been established and the rejection should be withdrawn.

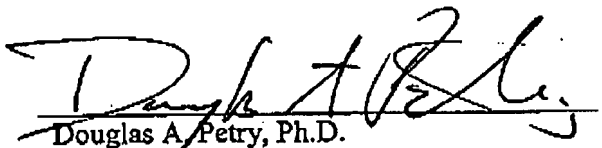
Applicants request reconsideration and withdrawal of the rejection of claims 17-32 under 35 U.S.C. §103(a) in view of the amendments and remarks.

Conclusion

Applicants believe that all rejections applied to the claims have been overcome and that the present application is now in condition for allowance.

Respectfully submitted,

6/1/07
Date



Douglas A. Petry, Ph.D.
Reg. No. 35,321
Agent for Applicants
Customer No. 26253
Tel: (408) 518-5074
Fax: (408) 954-4122